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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/528,056

03/15/2005

Josef Seidl

23241

9037

21186

7590

01/23/2009

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EXAMINER

HOBBS, MICHAEL L

ART UNIT

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1797

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/528,056	<b>Applicant(s)</b> SEIDL ET AL.	
	<b>Examiner</b> MICHAEL HOBBS	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 14-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/28/2008</u>  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Applicant's amendment filed on 10/24/2008 has been considered and entered for the record. Applicant's amendment filed on 10/24/2008 overcomes the objection to the specification in paragraph 1 and overcomes the 35 USC 1112 second paragraph rejection in paragraph 3 of the Office Action mailed on 07/24/2008. Applicant's amendment overcomes the 35 USC 102(b) rejection in paragraph 12 and the 35 USC 103(a) rejection in paragraph 25 of the office action mailed on 07/24/2008. Newly added claims 14-34 are pending examination upon the merits.

### ***Claim Objections***

2. Claim 15 is objected to because of the following informalities: on line 1 of the claim, the applicant states that the observation system "recognizes stoed contours". The Examiner believes this to be a spelling error and has interpreted this to be recognizes stored contours instead. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 14-21 and 23-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kearney (US 5,424,209) in view of Blumenfeld et al. (US 2003/0151735 A1).

7. For claim 14, Kearney discloses an automated cell culture device that includes a bioreactor or cell culture chamber includes a heating element or incubation equipment for cultivating cells (col. 5 lines 59-62; col. 6 lines 24-26). The bioreactor and heating element are fully capable of adjusting the conditions within the bioreactor to individual cell lines if needed. Kearney further discloses that the bioreactor can be used with an

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automated microscope/CCD and a robotic X-Y-Z translator (col. 20 lines 25-28), but does is silent regarding the software or the optics assembly.

8. Blumenfield discloses a CCD (CCD 608) or camera that includes a viewing optics assembly (assembly 617) which is being interpreted as a microscope attachment and where the CCD and optics assembly are attached to a moveable platform (platform 620; [0170]; [0181]). The carriage moves the lens across the slide during scanning where this movement is controlled by a computer implementing software ([0055]). Therefore, it would be obvious to one of ordinary skill in the art to employ the optics system as suggested by Blumenfield in order to observe the cells of Kearney. The suggestion for doing so at the time would have been in order to scan or image a biological sample or a portion of that sample ([0047]).

9. For claim 15, the camera of Kearney is fully capable of recognizing stored contours when the camera is indexed.

10. Regarding claims 16, and 27, Kearney discloses that culture media is sent to the bioreactor from sample reservoirs (2) via fluid pathways where the nutrient media is oxygenated by a gas source such as a pressurized gas bottle (col. 6 lines 1-3, 12-14). The nutrient media and gas source are fully capable of providing a continuous source of culture media and gas to the bioreactor. Furthermore, the heating of the bioreactor is controlled by a heat sink with a Peltier-type heating/cooling unit that includes an embedded heat sensor for monitoring temperature (col. 6 lines 24-26). The temperature sensor is connected to an on-board computer or controller that controls the operation of the Peltier heating/cooling device (col. 6 lines 27-30). Morphological

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analysis of the cells occurs through an automated microscope or CCD camera system (col. 20 lines 25-28). Also, cell parameters such as dissolved oxygen content of the media or acidity are sensed by flow cell electrodes within the flow cell (col. 15 lines 32-34). The data from these electrodes form the basis for software controlled decisions to refresh the volume of gas within the oxygentator (col. 15 lines 34-37, oxygenator 6). The computer and software are fully capable of optimizing the conditions within the bioreactor based on feedback from the sensors.

11. With regards to claims 17 and 18, Kearney discloses that the bioreactors are connected in series (col. 20 lines 43-45) or in parallel (col. 6 lines 1-2).

12. For claims 19 and 20, Kearney also discloses a circulating peristaltic pump for circulating the media through the plurality of pathways (col. 5 lines 63-67) and that the gas flow is controlled by a series of T-unions (38,112) that direct the airflow through a high pressure valve and into a membrane oxygenator (oxygenator 6; col. 14 line 66 through col. 15 line 4). Regarding claim 21, the embedded temperature system was discussed above.

13. With regards to claim 23, Kearney discloses monitoring the temperature which is being interpreted as permanent monitoring of the temperature as discussed above. Kearney discloses a computer to control the action of the bioreactor which receives data from the sensors such as microscopic observation of the cells, temperature measurement and measuring cell parameters such as pH. The computer uses this data to control the reaction as was discussed above. Also, for claim 24, data from the sensors was analyzed by soft-ware as was discussed above.

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14. Regarding claim 25, Kearney further discloses that bioreactors are mounted within recess of the aluminum heat sink that includes the heating element (col. 6 lines 24-26). Furthermore, it would be obvious to one of ordinary skill in the art to employ a plurality of culture chambers in order to increase the throughput of the process. See MPEP 2144.01 VI (B). For claim 26, the chambers of Kearney are fully capable of providing indirect co-culturing.

15. With regards to claims 28 and 29, Kearney discloses that the bioreactors are connected in series (col. 20 lines 43-45) or in parallel (col. 6 lines 1-2).

16. For claims 30 and 31, Kearney also discloses a circulating peristaltic pump for circulating the media through the plurality of pathways (col. 5 lines 63-67) and that the gas flow is controlled by a series of T-unions (38,112) that direct the airflow through a high pressure valve and into a membrane oxygenator (oxygenator 6; col. 14 line 66 through col. 15 line 4).

17. With regards to claim 32, Kearney discloses monitoring the temperature which is being interpreted as permanent monitoring of the temperature as discussed above. Kearney discloses a computer to control the action of the bioreactor which receives data from the sensors such as microscopic observation of the cells, temperature measurement and measuring cell parameters such as pH . The computer uses this data to control the reaction as was discussed above.

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18. Claims 22, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kearney (US 5,424,209) in view of Blumenfeld et al. (US 2003/0151735 A1) and in further view of Pfaller (US 6,329,195 B1).

19. Kearney and Blumenfeld are silent regarding a gas-permeable membrane with cells on both sides of the membrane.

20. Pfaller discloses a cell culture for continuously supplying culture media to the cells via inflow and outflow openings. For claims 22 and 33, Pfaller discloses that the culture chamber is divided by a gas-permeable membrane (5) where the membrane can culture to mono-layers of cells. The inlets and outlets provide for the continuous and homogeneous replacement of culture medium (col. 2 lines 55-58). Also, two different nutrient compositions can be perfused through the top (apical) and bottom (basal) side of the growth support (col. 2 lines 58-62). Since Pfaller discloses that two different culture media can be perfused through the culture chamber, it would be obvious to one of ordinary skill in the art to employ the double chamber of Pfaller in order to co-culture the cells within Kearney and Blumenfeld. The suggestion for doing so at the time would have been in order to provide organotypic culture conditions within the chamber (col. 2 line 62).

21. With regards to claim 34, Kearney discloses monitoring the temperature which is being interpreted as permanent monitoring of the temperature as discussed above.

Kearney discloses a computer to control the action of the bioreactor which receives data from the sensors such as microscopic observation of the cells, temperature



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measurement and measuring cell parameters such as pH. The computer uses this data to control the reaction as was discussed above

### ***Response to Arguments***

22. Applicant's arguments with respect to claims 14-34 have been considered but are moot in view of the new ground(s) of rejection.

23. The new grounds of rejection were necessitated by amendment and regarding applicant's argument on page 8 paragraph 5 that Kearney and Pfaller do not supply the video-assisted camera, microscope attachment, a displaceable table and software. This deficiency is corrected by the applied reference of Blumenfeld which discloses a CCD and optics assembly which are attached to a moveable carriage in order to perform an optical scan of a microscope slide.

### ***Conclusion***

24. Claims 14-34 are rejected.

25. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL HOBBS whose telephone number is (571)270-3724. The examiner can normally be reached on Monday-Thursday 7:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/  
Primary Examiner, Art Unit 1797

/M.L.H./  
MICHAEL HOBBS  
Examiner, Art Unit 1797

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